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Washington, D.C. 20004

In Re: Patent Term Extension
Application for
U.S. Patent No. 4,309,445

LETTER REGARDING IMPROPER PAPER

This is in response to the "Application of Barr Laboratories, Inc. for Suspension of 37 C.F.R. § 1.765(d) in Respect of the Pending Application for Extension of the Term of U.S. Patent No. 4,309,445," and to the "Public Protest Against Term Extension Application for U.S. Patent No. 4,309,445," filed August 27, 1997.

The petition under 37 CFR 1.183 is dismissed.

The papers filed August 27, 1997 are returned herewith.

37 CFR 1.765(d) specifically states that submissions from third parties with respect to applications for patent term extension will be returned. This rule tracks the statutory intent that the determination of eligibility for extension of the patent term by the Commissioner be made on the basis of the application for patent term extension. See 35 U.S.C. § 156(e)(1). A cursory review of the papers filed August 27, 1997 reveals that the papers were not filed by the applicant for patent term extension and that they argue that the above-identified patent is not eligible for patent term extension based upon the regulatory review period of the drug product REDUX™.

37 CFR 1.183 permits waiver of the rules in an extraordinary situation, where justice requires such waiver. A third party paper attacking the eligibility of a patent for patent term extension is not an extraordinary situation, where justice requires waiver of a rule. In re Dubno, 12 USPQ2d 1153 (Comm'r Pats. 1989). Accordingly, the papers are returned herewith.

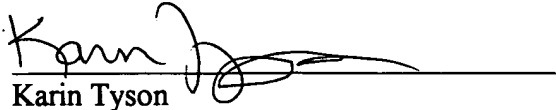
Any correspondence with respect to this matter should be addressed as follows:

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By FAX: (703) 308-6916
Attn: Special Program Law Office

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Telephone inquiries related to this letter should be directed to the undersigned at (703) 305-9285.


Karin Tyson
Senior Legal Advisor
Special Program Law Office
Office of the Deputy Assistant Commissioner
for Patent Policy and Projects

Enclosure: "Public Protest," filed August 27, 1997 (four copies)
Petition under 37 CFR 1.183, filed August 27, 1997 (two copies)
Cover letter for Petition (two copies)

cc: Charles E. Van Horn
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